I. **Requested Waivers**

1. In item (a) on page 2, you have requested a waiver of section 1902(a)(10)(A) of the Social Security Act (the Act) to permit individuals with income up to 300% of the Federal poverty level to access services under the demonstration. A waiver of this provision would not provide any affirmative authority to provide Medicaid coverage to otherwise ineligible individuals. This requested expansion of eligibility must be accomplished under authority of section 1115(a)(2) of the Act, which permits the Secretary to regard as Federally-matchable those expenditures which would not otherwise be included as (matchable) expenditures under section 1903. Please revise you waiver request accordingly.

Response: The Department of Human Services (DHS) concurs with HCFA in the interpretation of this provision of the Social Security Act. DHS requests, that under the authority granted under section 1115 (a)(2) of the Act, the Secretary regard as Federally-matchable those expenditures under this demonstration project for individuals enrolled in the waiver who have adjusted gross income of up to 300% of the federal poverty guidelines (no resource test), which would not otherwise be matchable under Maine's current Medicaid State Plan.

2. On page 2, you have requested to waive certain provisions of title 16, specifically section 1613 and 1614 of the Act, concerning the State's disability regulations and resource limit regulations under the Supplemental Security Income program. There is no authority to waive these provisions (Note-The references to title 16 in section 1115 do not refer to title 16, the SSI program; rather, they refer to the former title 16 state plan program, which now applies to Guam, Puerto Rico and the U.S. Virgin Islands.) Again, if you wish to extend Medicaid benefits to otherwise ineligible individuals, section 1115 (a)(2) authority is needed. To get a fuller understanding of what you are planning to achieve in this demonstration and ensure that you have requested all of the necessary waivers, please explain why you believed you needed these waivers.

Response: The provisions of the Act requiring that an individual be disabled with AIDS disease before being eligible for SSI and thus Medicaid services, postpone necessary anti-retroviral drug treatment. The delay of this drug treatment makes the initial treatment more expensive, as evidenced by Maine's Medicaid experiences to date. The waiver program described in our application would be more cost effective if recipients are assured that once deemed disabled for AIDS disease, they would continue SSI eligibility (excluding cash payments). This would enable recipients to continue to access life-sustaining medical benefits, even when the progress of the disease is slowed with HAART, which in most cases is available to them only through Medicaid coverage.

Under the authority granted to the Secretary under Section 1115 (a)(2) of the Act, expenditures for persons who are diagnosed HIV positive, and have an adjusted gross income less than or equal to 300 percent of the federal poverty guidelines (with no resource test) would be included as federally matchable under this demonstration project.

3. In item (d) on page 2, you have requested a waiver of the amount, duration, and scope requirements in section 1902 (a)(10)(B) of the Act in order to offer a limited benefit package to waiver recipients. Please provide further clarification for this statement. If an individual is enrolled in the demonstration and later becomes eligible under the standard Medicaid program, will this person then have access to all Medicaid services?

Response: If a waiver recipient later becomes eligible for Medicaid in accordance with the current Medicaid State Plan, then they would be eligible for all services of the Medicaid Program and would be disenrolled from the waiver project.

4. In item (f) on page 2, you have requested a waiver of the residency regulations in section 1902(b) of the Act to impose an eighteen-month residency requirement for all demonstration eligibles. We believe that this durational residency requirement may be unconstitutional. We are thus not disposed to approve it.

Response: Given HCFA's disposition not to approve an eighteen-month state residency requirement for this demonstration program, Maine requests approval to cap the maximum number of eligibles enrolled in the program. The maximum number of eligible enrollees would be 300 individuals receiving services under the waiver program at any given point in time, which in essence gives the waiver program 300 enrollment slots. This would allow Maine to have some administrative control over potential in-migration that would adversely affect the budget neutrality of the waiver. Since the cost neutrality assumption is based on known cases in Maine, any large addition to this population would make cost neutrality an impossible goal to reach.

II. **Eligibility and Enrollment**

1. As part of the evaluation process, we would like to have a better understanding of the size and character of Maine's HIV/AIDS population, and more specifically, the HIV/AIDS population being served by Maine's Medicaid program.

Estimated number of people living with AIDS in Maine (and the proportion of these individuals that currently rely on Medicaid);
Estimated number of people living with HIV (symptomatic and asymptomatic);
Estimated number of people living with HIV who may be enrolled in Medicaid due to eligibility under an existing eligibility category;

Demographic characteristics of the HIV/AIDS population (e.g., gender, race/ethnicity, age, exposure category/risk behavior);
Information regarding the socioeconomic status of people with HIV/AIDS who are not currently Medicaid eligible;
Information regarding the insurance profile of people with HIV/AIDS who are not currently Medicaid eligible; and
Percentage of HIV+ individuals who are served by Ryan White providers.

Response A: Estimates of AIDS and proportion on Medicaid. Maine has 379 living reported cases of AIDS (86% male and 14% female). The individuals living with AIDS are primarily adults. Ninety percent (90%) of the individuals with AIDS are white, five percent (5%) African American, four percent (4%) Latino/a, and one percent (1%) each are Asian/Pacific Islanders and American Indians. Seventy-seven percent (77%) of the people are between 30 and 49 years old. Four percent (4%) are between 20 and 29 years old, twelve percent (12%) between 50 and 59 years old, five percent (5%) over 60 years old and the remaining two percent (2%) are under 19 years old. Over half of these individuals live outside of metropolitan areas.

Risk has been attributed as follows:

Men who have sex with men 56%
Injecting drug users 14%
Men who have sex with men who also inject drugs 3%
Heterosexual 11%
Hemophiliac 3%
Perinatal 2%
Transfusion 1%
Unattributed risk 10%

Estimated number of persons living with AIDS disease who are on Medicaid: approximately 60%.

Response B: Maine has an estimated 950 to 1,300 people living with HIV. The mid-point figure used for planning purposes is 1,125. This figure was derived by using a CDC formula which uses the ratio of reported AIDS cases to estimated national sero prevalence an applies that same ration to Maine AIDS cases.

Response C: Estimated number of persons living with HIV disease who are on Medicaid: approximately 22%.

Response D: Demographics In 1998 ninety percent (90%) of those tested positive were male and ten percent (10%) were female. All of those testing positive were adults; thirteen percent (13%)

were 20 – 29 years old, forty-five percent (45%) were 30 – 39 years old, nineteen percent (19%) were 40 – 49 years old and twenty-three percent (23%) were over 50 years old. Risk for those who tested positive were attributed as follows:

Men who have sex with men – 44%
Injecting drug users – 13%
Men who have sex with Men and also inject drugs – 3%
Heterosexual – 38%
Transfusion – 3%

Response E: The following proportions are derived from reports testing HIV+ in 1995 and 1996. No such data exists for persons with AIDS. Therefore, only the percentages (weighted) are noted:

Homeless – 7.6%	Unemployed – 48.4%
Mentally Ill – 11.5%	Substance Abusing (Non-injectable) – 39.5%

Response F: A study of a small number of patients with an HIV diagnosis was selected from the Maine Medical Center's AIDS Consultation Service. Of the patients in need of and eligible for the waiver and not on Medicaid, one third (1/3) had some form of private insurance coverage. We infer that the private insurance coverage is not complete and that it would cover one third (1/3) of the total cost of care for HIV and therefore those with a prescription drug benefit would be about 10% for those people with insurance. The State of Massachusetts reports that 10% of individual newly insured through Medicaid have come into their program on insurance continuation. The Bureau of Medical Services suspects that the experience of this group might will mirror that of the target population being considered for this HIV waiver.

Response G: Low income individuals who do not qualify for Medicaid receive their care through their local system of care, but their cost of care is usually covered by local case management agencies using Title II and locally raised funds, hospital indigent care programs, and two of the three locally funded city departments.

The State of Maine currently has six AIDS case management programs. Five of the six programs are recipients of Title II funds, the sixth is a Maine Community AIDS Partnership funded by Portland Public Health program targeting the homeless. These programs provide a full array of Ryan White services as well as many additional supportive services which include housing assistance, food banks, individual and family support groups, emergency financial assistance, respite care, transportation, and buddy services.

The Maine AIDS Drug Assistance Program is managed collaboratively between the ACL Service center and the HIV/STD Program at the Maine Bureau of Health. The budget includes Ryan White Title II funds designated for ADAP and a state allocation of $60,040. Enrollment is limited to people with HIV who have income below 200% of poverty as well as a CD4 less than

400 or a viral load of over 20,000. The formulary includes all HIV related medication, but the program has instituted a 24-person cap on Protease Inhibitors.

Primary care is provided through private practice primary care physicians across the state. The state's largest hospital, Maine Medical Center provides a statewide consultation service (AIDS Consultation Service "ACS."). A sample taken from the Maine Medical Center's AIDS Consultation Service indicated that nearly 80% received some service through the Ryan White program. Of this sample, 70% received case management services, 36% received some drugs through the ADAP program, and 26% received both case management and ADAP assistance.

2. In order to help understand the demonstration better, we would like to learn more about the population that will be enrolled in the waiver. Please provide the following information regarding the size and character of the target population. As part of you response, please provide the following information to the extent that it is available. We understand that some of the following may be difficult to obtain prior to enrollment.

Insurance status prior to enrollment (e.g., uninsured or inadequately insured);
For those who were insured, percentage enrolled in public (Veteran's Administration, Medicare) versus private insurance;
Whether individuals currently have access to appropriate care; and
Percentage of the target population who are Ryan White recipients.

Response A: A study of a small number of patients with an HIV diagnosis was selected from the Maine Medical Center's AIDS Consultation Service. Of the patients in need of and eligible for the waiver and not on Medicaid, one third (1/3) had some form of private insurance coverage. We infer that the private insurance coverage is not complete and that it would cover one third (1/3) of the total cost of care for HIV and therefore those with a prescription drug benefit would be about 10% for those people with insurance. Maine's findings are supported by reports from the Massachusetts Medicaid experience. The State of Massachusetts reports that 10% of individuals newly insured through Medicaid have come into their program on insurance continuation. The Bureau of Medical Services suspects that the experience of this group might well mirror that of the target population being considered for this HIV waiver.

Response B: A sample taken from the Maine Medical Center's AIDS Consultation Service indicated that 10% of individuals in the sample had Medicare coverage. Insufficient information is available on individuals with benefits from the Veteran's Administration.

Response C: The basic assumption of the waiver is that those individuals targeted for inclusion under the waiver are unable to have any, or uninterrupted, access to HAART and are therefore not able to access appropriate care. Additionally, some individuals either have access to some

drugs or are receiving care at sub-optimal levels. The objective of this demonstration project; therefore, is to offer access to optimal levels of HAART therapy as the standard for appropriate care.

Response D: A sample taken from the Maine Medical Center's AIDS Consultation Service indicated that 62% of individuals in the sample who were receiving some form of Ryan White service might be appropriate for a transition to the waiver. Of this sample, 33% receiving case management services, 8% receiving some drugs through the ADAP program, and 21% received both case management and ADAP assistance were considered appropriate for a transition to the waiver.

The ADAP program requires that individuals present at, (a) an advanced level of HIV disease, (b) have income levels below 200% of poverty, and (c) be within their service cap of 24 persons for those receiving Protease Inhibitors. There is a waiting list for the ADAP program. It would be reasonable; therefore, to expect to see a shift of the known ADAP participants as well as those on the ADAP waiting list or those with high Medicaid spend-downs onto the waiver.

3. What is the expected enrollment level of the demonstration? How will enrollment fluctuate over time? Are new entrants allowed to enroll in the demonstration once the initial population has been selected and enrolled?

Response: The expected enrollment level of the demonstration is 300. The waiver program will have 300 enrollment slots and as shown on our "Estimate of Population" (Waiver Attachment 1), we estimate there to be approximately 611 persons with HIV disease who are not on Medicaid. The enrollment will be constant over time, since when a slot is vacated due to death or transition to another payor source, another client who is identified as having HIV disease without assistance to pay for medical treatment would then fill the slot.

4. It is not clear whether individuals who are currently eligible for Medicaid will be enrolled in the demonstration. Page 1 implies that participants will be disenrolled from the waiver if they become Medicaid eligible, yet page 8 refers to individuals "on Medicaid under the waiver". Please clarify your intent and amend the proposal as necessary.

Response: We expect that there will be recipients who are presently Medicaid-eligible who will become ineligible for Medicaid and enroll in the Waiver program. Individuals would have the advantage of the increased income limit of 300% of poverty in the Waiver, and individuals need not be eligible for SSD/SSI in order to be eligible for the Waiver, whereas disability is a requirement for continued Medicaid eligibility. At the same time, we expect that a proportion of Waiver recipients will, over time, become eligible for Medicaid and will be moved from the Waiver benefit to the traditional Medicaid benefit.

Another point warrants explanation as well. Our model shows two cost models for the population of individuals in each disease category who are eligible for Medicaid (i.e., Waiver Medicaid, and non-Waiver Medicaid). The only difference between the two cost models of Medicaid-eligible clients is the presence of an additional drug rebate for anti-retroviral drugs because of the presence of the Waiver program. We make this assumption because, if the Waiver program is implemented, we expect that the additional rebate for anti-retroviral drugs will also be available for Medicaid clients with HIV infection.

5. On page 4, under the first bullet in number 3, the State assumes that all persons who ÿcontract AIDS will become Medicaid eligible. However, some persons may receive income that would exceed Medicaid allowable income levels. Given this possibility, please provide the basis for this assumption.

Response: This assumption is based on the fact that after a short time nearly all individuals will have spent down to Medicaid eligibility level or will become disabled, and their adjusted incomes would make them eligible for Medicaid benefits.

6. On page one, the State describes one of the eligibility criteria as, they (the enrollees) agree to comply fully with the course of treatment prescribedÿ. Full (100%) compliance with optimal drug therapy is also assumed in the cost model. However, many HIV providers have observed that even the most conscientious of HIV patients who are committed to their treatment regimen sometimes have difficulty with complete adherence. Please respond to the following:

How will compliance be defined?
How do you plan to assess a patients willingness and ability to adhere to the prescribed HIV treatment regimen as a condition of eligibility?
How will certain extenuating circumstances (such as drug use, homelessness, etc.) be accounted for?
Will individuals who fail to comply fully with the treatment be disenrolled from the program?
Will enrollees who experience treatment failure or substantial side-effects, which cause them to discontinue treatment, be disenrolled?
Once an individual is enrolled in the demonstration, how will providers then foster and measure patient adherence?
Is there a potential for coercion or other negative consequences of this requirement?

Response A: The essence of the Waiver program is the provision of HAART therapy and an essential package of associated healthcare services to patients with HIV infection. It is generally held by AIDS clinicians in Maine, that HAART therapy should be withheld in those situations in which patients are unwilling or unable to satisfactorily take the medications. We will rely largely upon the judgement and expertise of AIDS clinicians and case managers to start and

continue HAART therapy as a measure of ability and willingness to comply with treatment and thus of program eligibility. We would not expect to disenroll otherwise eligible patients from the Waiver program because of treatment failure or substantial side effects as a cause of discontinuance of HAART therapy.

We expect to measure compliance based on the results of therapy. We do not expect to see 100% compliance with therapy if 100% compliance were measured by means of pill counts. We will measure compliance mostly based on measures of control of the client's HIV infection. Based on the present experience of Maine AIDS clinicians, we are confident that we will see extremely high levels of compliance by these measurements. We also expect that disenrollment because of lack of patient compliance with therapy would be a very rare event. We plan to institute a clinical advisory panel, among other reasons, to help in the rare case where disenrollment might become appropriate.

Response B: Assessment of a patient's willingness and ability to adhere to the prescribed HIV treatment regimen will need to be defined on an individual basis. If full compliance is defined as an individual's adherence to the treatment plan tailored to their individuals needs and circumstances, than we expect to achieve substantial compliance with a patient's effort to attempt to take their drugs on an as prescribed basis. We believe this is a more realistic approach to base success on cooperation with physician and case managers than on an arbitrary end result that describes generically what set of drugs any given profile of patient should take.

Response C: The Bureau of Medical Services (BMS) expects to work with case managers as a group to develop and implement guidelines to work with targeted groups such as drug users and the homeless. The Bureau understands that some patients will have some difficulties with compliance with drug regimens and every effort will be made to make accommodation for those individuals who demonstrate a interest in working with their physicians and case managers to address any condition contributing to their non-compliance.

Response D: As noted earlier, assessment of a patient's adherence to optimal drug therapy will need to established on a case by case basis.

Response E: As described earlier, adverse side effects will be reasonable cause for deviation from a generally recommended guideline for drug regimen development.

Response F: The Bureau of Medical Services (BMS) intends to model, as a key feature of this demonstration, how decision support can enable physicians, case managers and other allied health professionals to better manage care through regular and timely access to patient information. BMS will be prepared to analyze and process pharmaceutical data on a timely basis, for example, and provide patient specific feed back to physicians and case managers. In

addition, since guidelines regarding HAART therapy is updated constantly BMS intends to work closely with its core group of providers with large HIV/AIDS patient case loads to assess when guidelines should be modified and distributed to all providers across the State. As well, BMS contracts with Goold Health Systems to perform Drug Utilization Review (DUR) and share relevant information to treating physicians which will contribute to better support of the quality of care delivered through their practice. BMS has had positive experiences in those instances when it has shared with physicians the difference between the experience of individual Medicaid patients and established drug-prescribing standards. Assumptions about what is optimal for each individual's patients will be established as regular dialog occurring during the decision support and drug utilization review process.

Other features of this demonstration project will include the use of specialized pharmaceutical edits and audits for both Medicaid HIV waiver and non-waiver Medicaid patients. Specialized edits will occur, live at the pharmacy, at the time drugs are dispensed. Pharmacists will be asked to review drug orders to monitor those instances when drug-drug combinations should not occur, are not generally recommended, such as when it is know that a drug effect is not likely to be sustained so as to prevent adverse or undesirable drug-drug interactions right up front (see waiver attachments 2-10), Recommended antiretroviral agents for treatment of established HIV infection).

It is anticipated that system support will regularly query patient information in order to monitor such things as optimal levels and timing of viral load testing. For example, clear guidelines have been established for the regular testing of patients at the time of a change in drug combinations and at regular intervals to measure the effect of the drugs and to monitor for any adverse side effects related to drug-drug and/or drug-disease interactions. Decision support will monitor patient information and share with individual physicians discrepancies between the experiences of individual Medicaid patients and those established guidelines. The Clinical Advisory Committee and the DUR committee will inform decision support as to the known probability of side effects associated with any given drug, or disease state, or for patients on investigational drugs, or for patients with specific conditions such as CMV retinitis. The Clinical Advisory Committee will further advise the Bureau on how to develop queries as well as advise on testing for physicians in order to minimize adverse drug effects.

Audits will occur at least monthly. Audit criteria will reflect some themes such as the concerns about how some drug-drug combinations may present long term side effects or the known probabilities around dug-disease interactions. This information will be offered to individual physicians so that they may weigh the pros and cons of their patients being on a drug at any given time.

Full compliance with optimal drug treatment cannot be mandated, but with enough resources placed into system support for this program, we expect to achieve near 100% compliance based

on reasonable exceptions. The Bureau of Medical Services intends to measure and improve adherence to optimal individual regimens by improving lines of communication and supplying timely and reliable treatment data to providers and case managers. To the extent that physical compliance of optimal drug therapies is possible, BMS believes that decision support will represent a significant system support.

Response G: The Bureau intends to support patients and their providers in the development of individualized regimens and care plans and to offer system supports that monitor the delivery of the highest levels of quality care. BMS does not anticipate coercion or other negative consequences.

7. What steps are you planning to take to provide notice of the demonstration's availability to the HIV/AIDS population? As part of your response, please provide an outreach plan.

Response: The Department will leverage existing resources and linkages in a multi-layer statewide effort to reach potential waiver enrollees. Utilizing existing programs and providers to increase awareness of and enrollment in Medicaid and the waiver program in a five layer approach consisting of: statewide awareness, targeted awareness, targeted efforts to enroll, assuring access to services, and monitoring of these efforts. (see waiver attachment 11)

8. Page 1 of the proposal also describes a situation in which people with AIDS become eligible for Medicaid; their health status improves as a result of drug therapy; and then their Medicaid eligibility is terminated because their health has improved (and presumably they are no longer classified as disabled). Please provide any available data to suggest that this is happening in Maine's Medicaid program.

Response: Given the limits of good data in this area, support of this statement is largely anecdotal at this time. What little hard data that is known, is based on the baseline population used to develop the baseline cost estimates (see response to section VII Other Concerns, Question 1). Based on that sample, we do know that about 10% of all HIV/AIDS clients had the experience of losing Medicaid eligibility for some period of time and then regaining eligibility at a later point. From some basic reviews of those cases we speculate that a common scenario to explain this occurrence would be seen in the experience of a patient with a prior disability related to mental health and/or substance abuse. Such individuals might be diagnosed and begin antiretroviral therapy while on Medicaid for a related disability. Such and individuals might look well enough over time to leave Medicaid, experience difficulty connecting with the AIDS Drug Assistance Program, stop taking their antiretroviral medications and return to Medicaid when they are sick enough to re-qualify for Medicaid. Another example would be a patient who left Medicaid, continued on a sub-optimal level of drug treatment and got sick enough to return to Medicaid.

III. **Premium Structure**

Introductory Note

The premium structure should be separated into two categories: (1) the premium that the individual actually pays and (2) the premium amount that is used in the cost model to calculate the actual savings to the Medicaid program. This latter amount is the "blended premium"

Premium Paid by the Individual

The actual premium paid by the individual is based only on the income of the individual and not on the stage of the individual's illness. The proposed monthly premiums are, as stated in page 6 of the original proposal:

Premium Level	Income Level (as a percent of poverty)	Monthly Premium
I	< 150%	0
II	150-200%	$20
III	200-250%	$40
IV	250-300%	$80

Premium Figure Used for Calculation in the Model (Blended Premium) The blended premium is created for ease of calculation in the cost model. The blend is based on the levels of income for a given stage of illness. For each stage of the illness, the blend is calculated by multiplying the percent of individuals each income level times the premium at that level and then totaling the values for the stage. For example, the blended premium for the symptomatic stage (Sx HIV) assumes that of those on the waiver who are Sx HIV, 38% will be at income level I, 25% at level II, 20% at level III and 17% at level IV. Thus, the monthly premium for each level was multiplied by the corresponding percentage and the resulting amounts added to form a blended premium for calculation purposes in the model for the Sx HIV stage.

Income Levels		Monthly Premium	Percent of Waiver Population Sx HIV	Blended Premium Sx HIV	
I	< 150%	0	38%	$0	(0 x .38)
II	150-200%	$20	25%	$5	(20 x .25)
III	200-250%	$40	20%	$8	(40 x .20)
IV	250-300%	$80	17%	$13.60	(80 x .17)

Blended Premium for Sx HIV used for Calculations in Model $26.60 (Total)

For individuals on the waiver, it appears that there is a different premium structure for each stage of the illness. Since the amount of the premium may vary on the individual's condition, please identify the period of liability for the different premium charges and how often the premium could change for health reasons. What would the amount of the premium be for each stage of the illness as you have defined it? What happens if an individual does not pay the premium? Did you consider other factors (e.g., family size) in calculating the premiums?

Response: The premium is based only on level of income and does not change by stage of illness. Standard Medicaid policies with regard to nonpayment of cost sharing will be followed. The premium structure is designed as percentage of poverty. Since poverty levels are tied to family size, the premium structure will also be tied to family size.

It is our understanding that the premiums will be monthly. If this understanding is correct, please amend Appendix B, Tables 9 and 10, to clarify this.

Response:

Table 9

Income as a Percent of Poverty	Percent Premium	Monthly Premium	Percent of Waiver Population ASx HIV	Blended Monthly Premium HIV ASx	Percent of Waiver Population Sx HIV	Blended Monthly Premium Sx HIV	Percent of Waiver Population AIDS	Blended Monthly Premium AIDS
<150%	0%	$ -	0.25	$ -	38%	$ -	50%	$ -
150-200%	25%	$ 20.00	0.25	$ 5.00	25%	$ 5.00	25%	$ 5.00
200-250%	50%	$ 40.00	0.25	$ 10.00	20%	$ 8.00	15%	$ 6.00
250-300%	100%	$ 80.00	0.25	$ 20.00	17%	$ 13.60	10%	$ 8.00
Total Blended Premium				$ 35.00		$ 26.60		$ 19.00

Total Blended Monthly Premium Adjusted for Inflation are shown in Table 10

Table 10

Period	Monthly Premium	Blended Monthly	Blended Monthly	Blended Monthly

		Premium Asx	Premium Sx HIV	Premium AIDS
0	80	$ 35.00	$ 26.60	$ 19.00
1	82	$ 35.88	$ 27.27	$ 19.48
2	84	$ 36.77	$ 27.95	$ 19.96
3	86	$ 37.69	$ 28.65	$ 20.46
4	88	$ 38.63	$ 29.36	$ 20.97
5	91	$ 39.60	$ 30.10	$ 21.50
6	93	$ 40.59	$ 30.85	$ 22.03
7	95	$ 41.60	$ 31.62	$ 22.59
8	97	$ 42.64	$ 32.41	$ 23.15
9	100	$ 43.71	$ 33.22	$ 23.73
10	102	$ 44.80	$ 34.05	$ 24.32

The blended premiums were used in the cost model to determine the cost reduction. The actual premiums that individuals would pay are based on their level of income as a percent of poverty and are shown in Table 10B. The actual premium is increased each 6-month period due to inflation. In this case, the highest income group (250% < 300%) begins with a premium of $80 and the inflation rate is 5% annually for everyone.

Table 10 B. Premiums Based on Percent of Poverty

Period	<150%	150-200%	200-250%	250-300%
0	0	$20	$40	$80
1	0	$21	$41	$82
2	0	$21	$42	$84
3	0	$22	$43	$86
4	0	$22	$44	$88
5	0	$23	$45	$91
6	0	$23	$46	$93
7	0	$24	$48	$95
8	0	$24	$49	$97
9	0	$25	$50	$100
10	0	$26	$51	$102
11	0	$26	$52	$105
12	0	$27	$54	$108
13	0	$28	$55	$110
14	0	$28	$57	$113

3. The text at the top of page 2 indicates that the premiums are adjusted by income and disease status. Although the titles of the columns in Tables 9, i.e., Blended Premium also infer this, the table does not appear to reflect an adjustment in premium based on disease status. Neither does the list of premiums on page 6. On page 8, the last paragraph of the text states, the premium is

reduced as the stage of the illness worsens. Please clarify.

Response: HCFA Question notes that the text at the top of page 2 indicates that the premiums are adjusted by income and disease status. Also, Page 8 of the Waiver document, **Premiums and Monthly Costs** infers the same assumption. These statements are errors in the application. As stated above, premiums are adjusted only by income, not by disease status.

4. In Table 10, we noted that the amounts in the 3 columns labeled blended premium Asx, blended premium symptomatic HIV, and blended premium AIDS do not add up to the amount in the premium column. Please explain the methodology used to arrive at the amount in the premium column.

Response: The question assumes that the premium blending is performed horizontally, be stages of illness. This is a mistaken assumption. Our premium blending is performed vertically, by income levels, with a separate distribution of income level for each disease stage.

Benefit Package

1. You are proposing to offer a benefit package consisting of (a) highly active antiretroviral therapy (HAART); (b) other medications covered by Medicaid; (c) office visits; (d) laboratory services; (e) case management services; and (f) hospitalization. Please provide further detail describing what is included in each of these service categories. In your description, please specifically address the following:

- What is included under office visits? For example, is a visit with a nurse covered for purposes of patient education and treatment adherence interventions? Is the office visit restricted to an ambulatory setting or does it include a hospital-based outpatient program (e.g., Maine Medical Centers AIDS consultation services)?
- Are office visits and drugs only available for HIV/AIDS-related health concerns? If so, how will it be determined whether or not an illness or condition is related to the persons HIV status and therefore if it is a covered condition?
- How do you propose to ensure that individuals enrolled in the demonstration receive needed services if those services are not in the demonstrations benefit package?
- What laboratory tests are included in the benefit package? Will the tests only include those for monitoring the progression of HIV or will it also include other diagnostic tests for related conditions, such as sexually transmitted diseases or cancer?
- Please describe what services constitute case management service? Does this include outreach, transportation and services to promote treatment adherence?
- Is prevention counseling covered under any of the services categories? People with HIV

need to be counseled about practicing safe sex and not sharing needles in order to protect others and to protect themselves from other diseases which could be difficult to treat and could complicate the management of their HIV infection. Some sexually transmitted diseases, such as cytomegalovirus and herpes simplex virus, act as opportunistic infections. Other STDs make it more likely that they will transmit HIV to others. Finally, persons with HIV should avoid acquiring other HIV strains which could be drug resistant and complicate their medical management.

Response A-F: The benefit package in the waiver application includes all physicians and other medical provider visits in independent and hospital-based practice settings, all medications, all laboratory studies, all hospitalizations, behavioral health/substance abuse services, and all case management services, the original waiver application did not include all these benefits. The 7 year cost neutrality model includes these expanded benefits (see waiver attachment 12). Although other social service costs would be covered as well, case management is generally provided by community AIDS workers in programs that were set up under the Ryan-White act. The original application did not include hospitalization coverage. We have changed the application to include hospitalization coverage, although our utilization assumption is for a low rate of hospitalization. The experience of Maine AIDS clinicians is that HAART therapy allows for patients to be essentially healthy and for hospitalization to be a rare event.

CDC funded HIV prevention programs fund prevention counseling service for people with HIV. These services are provided through contracts with the same agencies that provide HIV case management services. The HIV/STD program in Maine is collaborating with the ACL Service Center staff to implement a training program for case managers addressing sexually transmitted disease and Hepatitis, HIV prevention, confidentiality and record maintenance and working with the deaf community.

2. The proposed benefit package appears not to cover mental health and substance abuse services. Yet, these services, as well as other ancillary services, can be important for improving patient adherence to a HAART regimen. If such services are needed by waiver recipients, how do you propose to provide access to these services?

Response: See response to question IV. 1., above.

3. In the event that some waiver recipients have private insurance coverage, please explain how might the waiver benefit package wrap around someone's private insurance?

Response: The Code of Federal Regulations and state policy require Medicaid be the payor of last resort. The Department administering the Medicaid program must take reasonable measures to determine the legal liability of third parties to pay for services furnished under the program. Third party means any individual, entity or program that is or may be liable to pay all or part of

the expenditures for medical services furnished under the Medicaid program. Federal funding is not available if the Department fails to fulfill the requirement with regard to establishing liability and/or seeking reimbursement from a third party.

The Maine Department of Human Services, through its third party liability team, processes approximately $6 million in claims annually. These activities result in an annual saving of about $135 million through State and Federal recovery and cost avoidance.

V. Service Delivery System/Provider Network

1. Please describe the current HIV/AIDS service delivery system in the State and the patients it serves. What is the general configuration of Ryan White-supported providers (e.g., type of providers, services offered) as well as the AIDS Drug Assistance Program, and the characteristics of the clients they serve? Where do low-income people with HIV/AIDS who do not qualify for Medicaid currently receive their care?

Response: The state of Maine is a geographically large state with a population of close to 1,228,000 people. It is a low HIV incidence state. While many of those living with HIV live in the more populous southern counties, others are spread out all over the state, with some cases reported in each of the sixteen counties. Maine's continuum of care for individuals living with HIV is made up of both formal and informal structures and relationships, large specialized care providers and small local programs.

Primary care is provided through private practice primary care physicians across the state. The state's largest hospital, Maine Medical Center provides a statewide consultation service (AIDS Consultation Service "ACS."). ACS provides consultation to primary care physicians through a statewide toll free line, professional education to clinicians, and publishes a quarterly newsletter with the latest treatment developments. A second specialty clinic is being implemented at St. Joseph's Hospital in Bangor to serve the northern areas of the state.

The primary care needs of under-served populations, (those with multiple diagnoses and those in rural areas) have received increased attention over the last year. A collaborative work group in southern Maine applied for and received a Title III planning grant and late in 1998 were awarded a Title II grant to serve people with multiple diagnoses. This project is in the early stages of implementation and is well connected to the existing service system. Similar collaborative work groups applied for and were awarded a Title II planning grant for services in the central and northern regions of the state. That planning process is well under way and includes case management and clinical providers, people living with HIV and representatives of the Maine Department of Human Services and the ACL Service Center.

The State of Maine currently has six AIDS case management programs. Five of the six

programs are recipients of Title II funds, the sixth is a Maine Community AIDS Partnership funded Portland Public Health program targeting the homeless. These programs provide a full array of Ryan White services as well as many additional supportive service which include housing assistance, food banks, individual and family support groups, emergency financial assistance, respite care, transportation, and buddy services. These agencies make extensive use of volunteers and local fund raised money to provide support and assistance to people living with HIV.

The Maine AIDS Drug Assistance Program is managed collaboratively between the ACL Service center and the HIV/STD Program at the Maine Bureau of Health. The budget includes Ryan White Title II funds designated for ADAP and a state allocation of $60,040. Enrollment is limited to people with HIV who have income below 200% of poverty as well as a CD4 less than 400 or a viral load of over 20,000. The formulary includes all HIV related medication, but the program has instituted a 24 person cap on Protease Inhibitors. A number of Maine residents get their Protease Inhibitors through drug company compassionate use programs. The program is well connected to case management agencies, clinical providers and hospitals.

The Office of Substance Abuse services in the department of Mental Health, Mental retardation, and Substance Abuse Services supports several HIV prevention programs across the state. Five of these programs are targeted to dually diagnosed individuals and provide for HIV prevention education and treatment for Injecting Drug Users in conjunction with their drug abuse treatment.

Individuals with HIV can access mental health services through community mental health centers, individual and group practices, or hospital inpatient and outpatient units. The availability of mental health services for low-income individuals is a problem which effects low income individuals with HIV.

Low income individuals who do not qualify for Medicaid receive their care through their local system of care, but their cost of care is usually covered by local case management agencies using Title II and locally raised funds, hospital indigent care programs, and two of the three locally funded city health departments.

2. Please describe the provider network that typically serves people with HIV/AIDS who are covered by Medicaid. Will the existing Medicaid provider network, however configured, be adequate to serve the expanded patient population?

Response: The provider network is comprised of the entire Medicaid provider community. The resources will be redistributed from acute care to chronic and preventive care under the waiver program

3. On page 1, the proposal refers to an assigned waiver program provider. Would this be a

primary care provider? What is the anticipated array of participating providers (e.g., their qualification, training requirements, expertise, types of services offered)? How will the State assure that participating providers have experience in treating HIV disease and managing the complex treatment regimen required?

Response: The Bureau of Medical Services will form a Clinical Advisory Committee to assist in a number of areas of interest to the Bureau and treating physician. The Advisory Committee will be instrumental in helping set optimal drug treatment guidelines (see waiver attachment 13 through 16), Recommended Antiretroviral Agents for Treatment of HIV Infection); protocols for drug-disease interactions, and giving clinical feedback on the overall compliance and success of the waiver demonstration on the outcomes of patients living with HIV/AIDS. In addition, it is anticipated that the Clinical Advisory Committee will be key in developing ways in which decision support can be most useful in informing clinical best practice across the State.

4. Please describe the criteria for identifying and assigning HIV-experienced providers to beneficiaries.

Response: It is anticipated that patients will use the existing health and support service provider networks as their primary form of physician referrals. The Bureau of Medical Services does not intend to interfere with existing patient/physician relationships. The Bureau intends to support patients and their provider networks in accessing quality health care in the form of early and continuous access to antiretroviral therapies. See question II.6 for information regarding system supports for physician practice.

5. How will participating providers be reimbursed? How will you identify and contract with providers of other services (e.g., specialists, laboratory, hospitals)?

Response: These services will all be delivered through the normal Medicaid fee-for-service reimbursement methods and amounts.

6. How will the waiver program providers coordinate with existing Ryan White providers? Will Ryan White providers be included among the pool of waiver program providers? If a person is currently receiving care from a Ryan White or another HIV care provider, how will continuity of care be assured when this person enrolls in the waiver?

Response: As described in II.1. The current Ryan White providers work through a well coordinated case management system. The case management providers are currently enrolled as providers in the Maine Medicaid Program. People living with HIV access services through an intake process at the agency that serves their geographic area. The intake process includes an income screening that would help the case managers make appropriate referrals for payment source. Individuals are covered under the Ryan White system until their eligibility for other payment sources is

determined. Referrals are made to local DHS Service Centers to initiate applications for Medicaid and other possible programs such as Food Stamps and Temporary Assistance for Needy Families. The current providers would continue to be the first step in the process and would refer individuals to the Waiver program as they currently do the conventional Medicaid, ADAP, etc.

1. Are there any reasons to be concerned with the potential disruption in care for persons on the waiver program who eventually qualify for full Medicaid coverage?

Response: No, there is an excellent transition procedure in place in the Bureau of Family Independence, which is the agency responsible for all eligibility criteria for all programs in Maine. The same agency will be providing eligibility determination for the waiver and Medicaid programs, hence there should always be a smooth transition from program to program. Additionally, as stated before the provider networks for both programs are the same, thus ensuring not problems when transitioning from the waiver to Medicaid.

2. What is the proposed structure of the provider network that will be participating in the demonstration? Will the network be fee-for-service or managed care? If the network will be managed care, to what extent will enrollment be mandatory and to what extent will demonstration enrollees have a choice of health plans? What appeals rights for coverage decisions will beneficiaries have?

Response: The provider network, reimbursement system and administrative framework will all be identical to the current Medicaid system. It would be fee-for-service with no managed care option.

VI Cost Model/Budget Neutrality

Introductory Notes:

The time frame of 1996 and 1997 was selected for analysis based on the completeness of records. Individuals were initially selected for analysis from among the Medicaid population using the MMDSS based on the following criteria: Records indicated that there was a prescription claim that matched GPI codes (121045, 121050, 121060, 121080, 121090) for the use of antiretroviral drugs; Claims records indicated that patients had an HIV diagnosis only; Records indicated the presence of a clinical condition associated with HIV/AIDS.

To further insure the accuracy of the process, a filter was developed to eliminate patients that would not be the subject of the waiver. First, any patient who was identified to have used antiretroviral drugs for prophylaxis was dropped from the analysis. For example, if a) records indicated ICD-9 code V01.7 was recorded in association with antiretroviral use for less than six weeks, or b) a

diagnosis of unsafe sex or accidental needle stick, the patient was excluded.

Once the basic groups of cases were selected, the first step in the analysis was to group individuals into the three categories of interest -- HIV/AIDS, Symptomatic HIV Infection, and Asymptomatic HIV Infection. Second, all data was arranged in six month periods for the first and second halves of 1996 and 1997, respectively. Diagnosis and prescription claims data were then arranged chronologically by patient. A protocol for classifying individuals into each group was developed. The protocols were as follows (see waiver attachment 18, Indicators).

Investigator's protocol for classification as AIDS

Patients were assumed to have an AIDS diagnosis if:

1.) In each six month period there was one or more claims with an ICD-9 code of 042.x or 043.x in any file: inpatient, nursing home, hospice, clinic or physician files.

2.) Regardless of if there was an ICD-9 code of 042, there were one or more claims with ICD-9 codes of 044.x and one or more ICD-9 codes for conditions associated with the Center for Disease Control AIDS surveillance case definitions (see waiver attachment 19, ICD-9 Codes and waiver attachment 20, AIDS Diagnosis), any file: inpatient, nursing home, hospice, clinic, physician files.

3.) Regardless of a specific diagnosed or defining case definition, there were one or more ICD-9 codes for conditions associated with the CDC AIDS surveillance case definitions and evidence that a patient was being prescribed antiretroviral therapies along with drugs used to treat associated conditions. For example, a patient might be receiving PCP drug therapies prophylactically.

Investigator's protocol for classification as Symptomatic HIV Infection

Patients were assumed to have Symptomatic HIV Infection if:

1.) In each six month period there was an ICD-9 code of 043 or 044 diagnosis on one or more claims.

2.) There was no CDC AIDS defining conditions but an individual did have to have treatment for either a recurrent vaginal candida or a recurrent outbreaks of herpes simplex. At least one condition reoccurring was viewed as indication of immune dysfunction.

Investigator's protocol for classification as Asymptomatic HIV Infection

Patients were assumed to have asymptomatic HIV infection if there was evidence of a diagnosis with an ICD-9 code of V08 without any other claims for AIDS defining conditions. For example, an individual may have had one episode of vaginal candida per six month period, or one episode of herpes simplex in a two year period. If, however; an individual was know to have had regular use of antiretroviral therapy (ART) without another diagnosis they were dropped into the Symptomatic HIV Infection group.

Additional checks were made against the original assumptions made during the patient classification process. For example, most patients had claims data for 1995, 1994 and or 1993. When such information was available, patient charts were reviewed to see if there was evidence of a prior claim that would have changed how they were classified into the first half of 1997. If such indications were present, the diagnosis classification would have been re-calibrated. A sample of charts were abstracted using the known list of Medicaid identification numbers of HIV+ patients and using decision support, a review was done to see if any charts had prior authorization (PA) decisions in order to further validate all diagnoses. Of a sample of 30 patients who had PA claims (e.g., request for a medical bed for home or durable equipment for use with prophylactic treatments for conditions such as PCP, or use of restricted drugs like amphetamines) not one reversal of category occurred.

1. On page 8 of the application, the total cost of providing drugs and services to people with HIV who are Medicaid eligible does not appear to be based on actual per member per month spending in Maine for people with HIV and AIDS. We would expect that actual cost data to be available for the Medicaid population based on the state's explanation of its database on page four. Please provide historical per member, per month costs (total spending/total clients identified as HIV+/AIDS) for the categories of asymptomatic HIV, and AIDS. Please provide data for both 1996 and 1997 that separately shows the costs for services and drugs. If possible, please also provide these data by eligibility category such that those who become eligible for Medicaid by meeting the SSI level of disability are distinguished.

Response: The actual Maine Medicaid per-member-per-month costs for HIV-infected clients for the years 1996 and 1997 are as follows. The data are categorized by diagnostic category (AIDS, HIV-Symptomatic, HIV-Asymptomatic, or no identifiable HIV diagnosis for the period), by year, and by Drug-or-Service (see waiver attachment 17). We cannot subcategorize the data based on the patient's Medicaid classification (SSI or other).

Dx	Year	Drug or Service	PMPM
AIDS	96	D	$1,170.02
AIDS	96	S	$1,369.14
AIDS	97	D	$1,172.20
AIDS	97	S	$1,229.29

HIVA	96	D	$381.61
HIVA	96	S	$553.22
HIVA	97	D	$455.49
HIVA	97	S	$529.00
HIVS	96	D	$852.12
HIVS	96	S	$564.59
HIVS	97	D	$832.05
HIVS	97	S	$888.65
None	96	D	$126.22
None	96	S	$1,237.86
None	97	D	$191.35
None	97	S	$1,348.45

2. For the "without-waiver" probability of rates of disease progression, can you explain your assumptions with historical data from your Medicaid experience? If not, how did you determine the rates of disease progression in the "without-waiver" scenario?

Response: Original, 5-Year Waiver Application - The without-waiver probabilities of disease progression in our original waiver submission were derived from data published in a paper from the Johns Hopkins University AIDS treatment program over a 3-year period from 1992 through 1995 (Journal of AIDS and Human Retrovirology, 14:223-231, 1997). First, we collapsed their 4 categories into 3 categories. Second, since our clinical disease classification system relies upon claims data and does not have access to CD-4 cell counts, the mapping system must be approximate. Finally, we assumed that virtually all patients with an AIDS diagnosis would have access to HAART therapy. We therefore adjusted downward the late-stage disease progression probabilities. In addition, we modified the without-waiver transition probabilities based on observations and inferences from the Maine Medicaid database.

Revised, 7-Year Waiver Application - In our revised submission we have further adjusted the no-waiver probabilities because, even the absence of a waiver a percent of the clients are assumed to be covered by Medicaid and through Medicaid to have access to HAART therapy. The Hopkins data were adjusted so that these clients' probabilities of disease progression were assumed to be intermediate (halfway) between those probabilities assumed for the waiver population and the Hopkins non-HAART probabilities. The one-half adjustment was applied because the clients expected to transition from Medicaid to the waiver are likely to be those clients who are subject to a spend-down before Medicaid eligibility. Those clients are likely to see interruptions in their HAART therapy.

3. You refer to using data from current literature and the clinical experience of Maine physicians in developing your assumptions for the transitional probability model. Please provide further information on these data sources (e.g., current literature citations,

reports of Maine clinical experience) and any other data sources that were used in developing your assumptions. Please provide a detailed explanation of the assumptions used to develop the probabilities for the slower rate of progression in the waiver program.

Response: Qualitative Data Gathering and Analysis - In the early stages of development of the waiver program, the Medicaid drug database was analyzed to find all physicians in Maine who wrote prescriptions to Medicaid clients for anti-retroviral drug therapy. This group of physicians was then surveyed by telephone to ascertain the number of HIV positive patients in each practice. We discovered that the Maine Medical Center AIDS Consultation Service (MMC-ACS) had by far the most clinical experience in Maine. No other physician surveyed had more than a handful of HIV positive patients. The Waiver-development team had several meetings and telephone conversations with MMC-ACS team to ascertain their experience. Finally, we had several consultations with the director of the AIDS program within the Maine Bureau of Health in order to estimate the number of people with AIDS and the number of people with HIV infection residing in Maine. We used a combination of information from the supplied bibliography together with the MMC-ACS experience to develop our assumptions.

Assumptions regarding Waiver Program Rate of Disease Progression - It is our belief that the combination of early intervention, continuous HAART therapy, excellent clinical care, and excellent case management support the disease progression assumptions as set forth in our model. The present Medicaid system fosters care only late in the progression of HIV infection because of the usual requirement that Medicaid clients must be considered disabled for the purpose of social security and the requirement that their income level be below federal poverty levels. In addition, it often imposes a spend-down requirement on medical expenditures. It is the experience of Maine AIDS clinicians that financial barriers to obtaining of HAART therapy, including Medicaid spend-downs, are the single largest cause of poor, incomplete, or intermittent adherence to HAART therapy. The demographics of the Maine HIV positive population shows more patients who have been infected with AIDS via MSM (male sex with men) or heterosexual transmission and relatively few individuals who have been infected with HIV via intravenous drug use. It is known that this group of HIV-infected individuals has better adherence levels than IV drug users. Also, Maine is a small state with a small, well-integrated and excellent clinical care delivery system for the care of HIV-infected individuals. Finally, the clinicians and the Maine Medicaid program have both the commitment and the information management tools to foster excellent case management. (see waiver attachment 21 – bibliography)

4. Please elaborate on the assumptions made in creating the hypothetical cohort. In doing so, please respond to the following questions:

How did you establish the probability of the various states of health of the individuals in the cohort?

You have assumed that a certain percentage of the cohort will have access to Medicaid at various stages of the disease. How were these assumptions derived?

What assumptions were made about the cohort's access to private insurance, the Ryan White program, state-funded treatments that might slow the progression of the disease, as well as, out of pocket costs for care?

Response: The distribution of individuals by disease state assumptions in our model are derived from the disease-state spectrum of patients cared for within the MMC-ACS. We take this population to be quite representative of the population of patients who will be eligible for the proposed waiver program. The MMC-ACS patient database was surveyed for patient payer status. This data was used to derive the Medicaid eligibility and third-party-liability (TPL) assumptions in the model.

5. How did you arrive at your assumptions regarding the costs of care for individuals with asymptomatic HIV or symptomatic HIV infection?

Response: The assumptions regarding the cost of care were derived from the actual Medicaid per-member-per-month costs for 1996 and 1997. In some cases, utilization assumptions were adjusted to allow for our expectation that the waiver population will have less co-morbidity than a diagnosis-matched HIV positive Medicaid population. The actual Medicaid PMPM costs are supplied above, in VI-1.

6. On page 8, the model shows only a $100 cost difference for non-drug treatment between the symptomatic HIV category and the AIDS category. Why is there so little difference in service costs between these two groups?

Response: The model provided with our original Waiver application had a substantial error in the utilization assumption for nursing home care in the HIV-Symptomatic population (0.5 units per month. The correct figure derived from actual data is .005 units per month.) This error resulted in an overstatement of expected PMPM in this population of almost $500 per month.

7. It appears as if the model assumes that no new individuals with AIDS, beyond those who would be on Medicaid anyway, would enroll in the demonstration? If this is accurate, what is the basis for this assumption?

Response: Our cost-neutrality model as submitted here is based on a fixed cohort of clients who would enroll at the beginning of the waiver program. It does not assume that new individuals would enroll over time in either the waiver or non-waiver programs. We will submit an additional model shortly in order to demonstrate cost neutrality with a slotted cap on the waiver population and a fluid Medicaid population.

8. The cost model has current law Medicaid costs under the heading of "No Treatment" even though the treatment transitional probabilities used in table 3 for PLWA in the no waiver case look similar to what is obtained with HAART. Are no Medicaid enrollees

assumed to be currently on HAART? If this is accurate, what is the basis for this assumption?

Response: The Cost Model had mis-titles. The title "No Treatment" should have been "No Waiver".

9. It appears from your waiver submission that you have begun counting waiver costs in the second semi-annual period. Just as a baby's first year begins at age 0 (and not age 1), the waiver costs for the first period start at point 0 and not point 1. By calculating the cost at point 1 instead of point 0, the model is, in effect, using the 2nd through 11th semi-annual periods instead of the first 10 semi-annual periods, 1-10. Please check your calculations and provide any necessary corrections.

Response: Waiver costs were shown as starting only in the second semi-annual period. This was an error, and has been corrected.

10. How are the costs for dual eligibles entitled to both Medicare and Medicaid being handled in the cost model?

Response: The costs shown for Medicaid include blended costs for Medicaid recipients who are dually eligible and costs for Medicaid recipients who are not dually eligible. The costs included for Medicaid recipients who are dually eligible are the Medicaid share of total costs – i.e., Medicare premiums, physician and hospital co-pays and deductibles. Thus, the model already includes the dually eligible population.

11. Page 10 contains an error in the "non-waiver cost" column. The total of the three numbers adds up to $10,239,588, not $10,207,907 as reported. Please verify the accuracy of these figures, and revise as necessary.

Response: This is true, and has been corrected.

12. Please provide a narrative explaining Table 4 on page 8.

Response: The narrative explaining Table 4 is provided in the four paragraphs preceding the table. They are derived form the Markov model and all components and abbreviations are defined in the original waiver document.

13. Please define "residential care" and "miscellaneous" categories of service in Table 1 on page 3. Where do these services fit in Appendix C, pages C-1 and C-2?

Response: Residency Care contains the following Medicaid categories: Physically Disabled Waiver, Private Non Medical Institutions, ICF/MR Boarding Homes, Boarding Home, and Waivered Boarding Home. Miscellaneous contains the following Medicaid categories: Transportation, Medical Supplies and DME, Ambulance, Unclassified, and HMO Waiver

14. Please explain your assumption that a higher percentage of individuals with symptomatic HIV will be eligible for Medicaid than those with asymptomatic HIV.

Response: This assumption is based on historical Medicaid claims histories taken from the MMDSS.

15. It is conceivable that the population who enrolls at the inception of the waiver program is likely to be, on average, at a more advanced stage of the disease than subsequent enrollees. Those who enroll in later years of the demonstration may be more recently diagnosed with HIV infection. Was this considered in your model? If so, please explain how.

VII Other Concerns

1. Public involvement is a critical part of any 1115 demonstration project. In your cover letter, you indicated that members of the community (e.g., providers, advocates, and consumers) were involved in the development of this demonstration proposal. Please describe the groups that have been participating and what their involvement has been.

Response: Through out the process of developing the application, Bureau of Health HIV/STD staff consulted with the Maine HIV Prevention Community Planning Group, the Maine HIV Advisory Committee and the ADAP Advisory Group. All of these groups include representatives of HIV community providers, advocacy groups and people living with HIV and function as advisors to state agencies who administer public funds for HIV related services. These groups were asked for input regarding the needs of the target population, the service package, and what additional sources of information might be useful. A community meeting was held which included the Bureau of Medical Services and Bureau of Health staff as well as case managers, clinicians, support program providers, and people living with HIV. Sections of the application were reviewed and attendees gave feedback and suggested additional sources of information.

2. How will the Portland Public Health Division (new Title III recipient) and the State Medicaid agency coordinate their activities under the demonstration project? Have any such discussions occurred or are any anticipated?

3. Assuring that enrollees are receiving quality care will obviously be of utmost importance, especially give the focus on HAART therapy. The proposal at this point does not address the development of quality assurance measures. What clinical standards will be used to assess quality of care (e.g., HHS guidelines for the use of antiretroviral therapies)? How will these standards be disseminated to providers? Will training be available?

Response: As noted in the response to question II..6 above, the Bureau of Medical Services

(BMS) intends to model, as a key feature of this demonstration, how decision support can enable physicians, case managers and other allied health professionals to better manage care through regular and timely access to patient information. BMS will be prepared to analyze and process pharmaceutical data on a timely basis, for example, and provide patient specific feed back to physicians and case managers. In addition, since guidelines regarding HAART therapy is updated constantly BMS intends to work closely with its core group of providers with large HIV/AIDS patient case loads to assess when guidelines should be modified and distributed to all providers across the State. As well, BMS contracts with Goold Health Systems to perform Drug Utilization Review (DUR) and share relevant information to treating physicians to better support the quality of care delivered through their practice. BMS has had positive experiences in those instances when it has shared with physicians the difference between the experience of individual Medicaid patients and established drug-prescribing standards. Assumptions about what is optimal for each individual s patients will be established as regular dialog occurring during the decision support and drug utilization review process.

Other features of this demonstration project will include the use of specialized pharmaceutical edits and audits for both Medicaid HIV waiver and non-waiver Medicaid patients. Specialized edits will occur, live at the pharmacy, at the time drugs are dispensed. Pharmacists will be asked to review drug orders to monitor those instances when drug-drug combinations should not occur, are not generally recommended, such as when it is know that a drug effect is not likely to be sustained so as to prevent adverse or undesirable drug-drug interactions right up front.

It is anticipated that system support will regularly query patient information in order to monitor such things as optimal levels and timing of viral load testing. For example, clear guidelines have been established for the regular testing of patients at the time of a change in drug combinations and at regular intervals to measure the effect of the drugs and to monitor for any adverse side effects related to drug-drug and/or drug-disease interactions. Decision support will monitor patient information and share with individuals physicians discrepancies between the experiences of individual Medicaid patients and those established guidelines. The Clinical Advisory Committee and the DUR committee will inform decision support as to the known probability of side effects associated with any given drug, or disease state, or for patients on investigational drugs, or for patients with specific conditions such as CMV retinitis. The Clinical Advisory Committee will further advise the Bureau on how to develop queries as well as advise on testing for physicians in order to minimize adverse drug effects.

Audits will occur at least monthly. Audit criteria will reflect some themes such as the concerns about how some drug-drug combinations may present long term side effects or the known probabilities around dug-disease interactions. This information will be offered to individual physicians so that they may weigh the pros and cons of their patients being on a drug at any given time.

Full compliance with optimal drug treatment cannot be mandated, but with enough

resources placed into system support for this program, we expect to achieve near 100% compliance based on reasonable exceptions. The Bureau of Medical Services intends to measure and improve adherence to optimal individual regimens by improving lines of communication and supplying timely and reliable treatment data to providers and case managers. To the extent that physical compliance of optimal drug therapies is possible, BMS believes that decision support will represent a significant system support.

4. Does the State intend to complete a civil rights assurance affirming that it will comply with all applicable Federal civil rights laws (such as Title VI of the Civil Rights Act of 1964; Section 504 of the Rehab. Act of 1973; the ADA of 1990, etc.) in the conduct of its program?

Response: The State intends to complete the necessary documents affirming that it will comply with all applicable Federal civil rights laws, as it has done for the Maine Medicaid Program and the Children's Health Insurance Program.

5. On page 6, what is meant by "pharmaceutical participation"? Do you intend to obtain discounts from pharmaceutical companies for the drugs covered by the demonstration? If so, will this discount be applied to only those enrolled in the demonstration?

Response: "Pharmaceutical participation" refers to additional discounts for HAART drugs. The State is seeking drug discounts for the HAART drugs for both the waiver program and the Medicaid Program.

6. Please explain how the third party liability statistics shown on page 6 were derived.

Response: A study of a small number of patients with an HIV diagnosis was selected from the Maine Medical Center's AIDS Consultation Service. Of the patients in need of and eligible for the waiver and not on Medicaid, 1/3 had some form of private insurance coverage. We infer that the private insurance coverage is not complete and that it would cover 1/3 of the total cost of care for HIV and therefore those with a prescription drug benefit would be about 10% for those people with insurance. Maine's findings are supported by reports from the Massachusetts Medicaid experience. The State of Massachusetts reports that 10% of individuals newly insured through Medicaid have come into their program on insurance continuation. The Bureau of Medical Services suspects that the experience of this group might well mirror that of the target population being considered for this HIV waiver.

7. As part of all 1115 demonstrations, States are required to provide detailed data regarding the impact of the waiver. Please describe in detail your data gathering capability and your ability to coordinate services for people with HIV.

Response: The Maine Medicaid Decision Support System is a Data Warehouse with a built in data extraction tool. MMDSS is a three tiered Client/Server system. The data

warehouse contains 5 years of claims data in addition to files such as, the provider and client files. The warehouse receives data from four different sources, MMIS, MEPOPS, MECAPS and Vital Statistics. Workers, with only desktop computer skills, can access data through the client data extraction tool. The data within the Data Warehouse can also be accessed directly through other software programs with an ODBC driver or directly with a product like SQL NET.

MMDSS was built to provided past and current data from multiple systems directly to line users as well as data analysts and report writers. MMDSS is to be used both within BMS and by other Bureaus, Departments, Agencies, and Companies. MMDSS takes advantage of the three tier Client/Server technology to provide a stronger data delivery system than had previously existed.

MMDSS has empowered users and units to create more detailed, comprehensive and flexible data analysis. It has opened up new paths of research, knowledge, and understanding to users and units that were not possible previously.

MMDSS has been used as a data source in the management of coordinated AIDS Services within the Medicaid program. The MMDSS has allowed BMS to do comparison studies of AIDS patients, Regions, Providers, and drugs. It has been used to perform costs based analysis of the AIDS program over time. It has been used to monitor the appropriateness of care and charges for the AIDS population. Data, and the ability to "mine" it real time in multiple iterations, from MMDSS was critical in the analysis that is currently going into the AIDS Waiver program.

The ability to get results instantly, to refine and rerun queries, to export results in a format that can be easily imported to a wide variety of analysis and reporting tools has allowed researchers and managers to have more control of their data and more flexibility in its use. It has given them a tool with which they can monitor the AIDS program and respond in a timely manner.

8. Page 1 of the proposal states "most health insurers do not fully cover HIV/AIDS disease and its essential package of services, most notably antiretroviral drugs". Please provide us with any available information regarding this issue in Maine.

Response: As noted in the response to question VII..6 above, a study of a small number of patients with an HIV diagnosis was selected from the Maine Medical Center's AIDS Consultation Service. Of the patients in need of and eligible for the waiver and not on Medicaid, 1/3 had some form of private insurance coverage. We infer that the private insurance coverage is not complete and that it would cover 1/3 of the total cost of care for HIV and therefore those with a prescription drug benefit would be about 10% for those people with insurance. Maine's findings are supported by reports from the Massachusetts Medicaid experience. The State of Massachusetts reports that 10% of individuals newly insured through Medicaid have come into their program on insurance continuation. The Bureau of Medical Services suspects that the experience of this group

might well mirror that of the target population being considered for this HIV waiver.